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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,997	FORSTNER, KLAUS	
	Examiner	Art Unit	
	MICHAEL R. BLOCH	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 April 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/3/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because Figure 4C contains hand written variables and a central equation that are difficult to read/decipher and should be rewritten to be clear, as the angles drawn appear to be theta and gammas, but it is not entirely clear.

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show xi, ny_1, ny_2, and the correct $delta_2$ equation (all in last paragraph p.17-18) as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities: p. 3 2nd paragraph contains double negatives "cannot not"; p. 11 paragraph 3 "psychic stress" apparently should read "psychological stress"; p. 16 first paragraph when describing Figure 4A the angles are improperly described as α, α', and β, β' which does not match the drawing, and should be α", α' and β", β' to match the drawing; p. 18 last paragraph it is unclear which of the two parallel results are calculated together when described as "both results" since there are three potential calculations in parallel that could be combined.

Appropriate correction is required.

5. The claims include reference characters which are enclosed within parentheses. The use of reference characters is considered as having no effect on the scope of the claims. Since the reference characters are not afforded patentable weight, the reference characters enclosed within parentheses apparently should be deleted from the claims. Correction is requested.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3-21 and 23-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Regarding claims 13 and 31, the claims contain the limitation “depending on a markedness”, however, this is indefinite as it unclear what the markedness refers to, how it is being used, and is not supported by special definition in the specification.

9. Claim 3 recites the limitation "the individual pulse oscillogram" in line 2. Claim 14 recites the limitation "the individual blood pressure" in line 5. Claim 16 recites the limitation "the error effects" in lines 3-4. Claim 16 recites the limitation "the hemodynamic instability” in line 3. Claim 17 recites the limitations “the individual pulse oscillogram” and “the hemodynamic instability” in lines 8-9. Claim 21 recites the limitation "the individual pulse oscillogram" in line 2. Claim 25 recites the limitations “the lengths of the pulse period”, “the starting range” and “the end range” in lines 2-3. Claim 32 recites the limitation "the individual blood pressure measurement" in line 4. Claim 34 recites the limitation "the error effects" in line 2-3. Claim 34 recites the limitation "the hemodynamic instability" in line 2. There is insufficient antecedent basis for these limitations in the claims.

10. Claims 4, 7-12, 15, 18-20, 26-30, 33 are rejected under 35 U.S.C. 112, second paragraph for being dependent on a rejected claims.

11. The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

> Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers

12. Claim 17 is rejected under 35 USC 112 4th paragraph, as being an improper dependent claim for failing to include all the limitations of the claim upon which it depends and for failing to further limit the subject matter of the claim upon which it depends. Specifically, claim 17 only

requires structure of an inflatable cuff capable of being connected to an elevating device and a unit for creating a pulse oscillogram, blood pressure determination device and a display device, and does not require actually performing steps determining a blood pressure from an oscillogram, performing an analysis of hemodynamic stability, obtain assessment criteria for a presence of the hemodynamic stability, and a correlation between blood pressure and hemodynamic stability of claim 1. Applicant should consider amending claim 17 so that it does not include any reference to claim 1. As the Federal Circuit treats non-compliance with 35 USC 112 4th paragraph as a patentability issue, it is considered more appropriate to treat a claim that does not comply with 35 USC 112 4th paragraph by rejecting the claim under 35 USC 112 4th rather than by objecting to such claim under 37 CFR 1.75(c) as provided for in MPEP 608.01(n)(II). See Pfizer Inc. v. Ranbaxy Labs., Ltd., 457 F.3d 1284, 1291-92 (Fed. Cir. 2006).

13. Claims 18-20 are rejected under 35 U.S.C. 112, fourth paragraph for being dependent on a rejected claim.

Claim Rejections - 35 USC § 101

14. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim(s) 1-16, 21-34 are rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter because these claims are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to a particular machine. See Diamond v. Diehr, 450 U.S. 175, 184 (1981) (quoting Benson, 409 U.S. at 70); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978) (citing Cochrane v.

Deener, 94 U.S. 780, 787-88 (1876)). See also In re Bilski , 545 F.3d 943, 88 USPQ2d 1385 (Fed. Circ. 2008), where the Fed. Cir. held that method claims must pass the "machine-or-transformation test" in order to be eligible for patent protection under 35 USC 101.

The claims do not pass the "machine-or-transformation test" because the method in claim 1 of determining a pulse oscillogram to detect a displayed blood pressure, conducting an analysis of hemodynamic stability, and obtaining assessment criteria for the presence of hemodynamic stability does not utilize a specific machine or does not transform an article or material, the blood pressure being displayed does not tie the process to a particular machine as a pulse oscillogram on a piece of paper meets the claim requirements and is not a particular machine or transformation of an article or material.

Examiner suggest inserting language directed to a particular machine that imposes a meaningful limit on the claim's scope, i.e. a machine that involves more than a field of use limitation and involves more than insignificant extra-solution activity.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-5, 8-10, 17, 18, 21-23, 26-28, 30, 31, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Forstner (Forstner, EP 1 258 233).

Regarding claim 1, Forstner discloses a blood pressure measuring method wherein a pulse oscillogram (PO) of a patient is determined and used to detect a blood pressure which is displayed (see p. 2 Lns. 42-43), the method comprising: while determining the pulse oscillogram (PO), performing an analysis of a hemodynamic stability (see p. 2 Lns. 49-50 where the results of diastolic and systolic blood pressures are automatically validated), wherein at least one of a hemodynamic parameter and at least one other physiological parameter which correlates with the hemodynamic parameter are evaluated with respect to chronological changes (see p. 2 Lns. 7-8 where diastolic and systolic blood pressures and pulse rate can be determined by the variation in the cuff pressure, see p.2 Lns. 52-56 where pressures and pulse rates are analyzed over time for steady increasing and decreasing); and obtaining assessment criteria for a presence of the hemodynamic stability from the analysis by which one of a determination of the blood pressure value and the determined blood pressure value is brought into a correlation to ascertain whether the blood pressure value was obtained during the hemodynamic stability, or that a corrected blood value is determined (see p.2 Lns. 52-56 where pressures and pulse rates are analyzed over time for steady increasing and decreasing patterns, and p. 4 Lns. 14-20 where results above the set limits are averaged to form a corrected value to reduce the affects of artifacts).

Regarding claim 2, Forstner discloses a warning indication is generated by an evaluation criteria if there is a deviation from one of a preset and a predeterminable threshold criteria (see p. 9 Lns. 36-38 where the basis measurements determine whether a patient is settled, if not a no-settling indication is displayed, and p. 9 Lns. where an indication is displayed to the user when verified conditions occur).

Regarding claims 3 and 21, Forstner discloses the individual pulse oscillogram (PO) is subjected to an analysis regarding the hemodynamic stability (see p. 2 Lns. 42-43, and p.2 Lns. 52-56 where pressures and pulse rates are measured oscillometrically and analyzed over time for steady increasing and decreasing patterns).

Regarding claims 4 and 22, Forstner discloses prior to obtaining the assessment criteria, influential values of at least one of artifacts and arrhythmia are suppressed (p. 4 Lns. 14-20 where results above the set limit are averaged to form a corrected value to reduce the affects of artifacts).

Regarding claims 5 and 23, Forstner discloses at least one of a pulse period progression , a pulse amplitude progression , and a pulse shape , is determined and analyzed from the pulse oscillogram (PO), and the assessment criteria from one of the pulse period progression, the pulse amplitude progression , the pulse shape , and a combined evaluation are formed from at least two items of base information (see p.2 Lns. 52-56 where pressures and pulse rates are measured oscillometrically and analyzed over time for steady increasing and decreasing patterns, p. 3 Lns. 29-31 where a variation index of results of blood pressure and pulse rate are determined for a series of data).

Regarding claims 8 and 26, an entire progression of all pulse periods in regard to their chronological change is determined and used as a measure for the hemodynamic stability (p. 3 Lns. 29-31 where a variation index of results of blood pressure and pulse rate are determined for a series of data).

Regarding claims 9 and 27, an entire progression of pulse-specific systolic times in regard to changes over time is determined and used as a measure of the hemodynamic stability

(p. 3 Lns. 29-31 where a variation index of results of blood pressure and pulse rate are determined for a series of data).

Regarding claims 10 and 28, Forstner discloses an assessment of the a constancy of the pulse period progression is included when forming the assessment criteria (see p. 2 Lns. 52-56 where the resulting measurements are verified that pulse rates are either steadily decreasing or increasing, p. 3 Lns. 29-31 where a variation index of results of pulse rate are determined for a series of data).

Regarding claim 17, Forstner discloses a sphygmomanometer for executing the method in accordance with claim 1, having an inflatable cuff and an evaluating device which can be arranged thereon or connected to it, with a unit creating the pulse oscillogram (PO), a blood pressure determination device and a display device, comprising the evaluating unit having an assessment arrangement embodied so that assessment criteria for the presence of hemodynamic stability are formed with it during the determination of the individual pulse oscillogram (PO), and the display device has an indicator of the hemodynamic instability (see p. 2 Lns. 4-8 where known monitors are used to measure blood pressures using oscillometric measurements by use of inflatable cuffs, abstract and Figure 1.1 where the results of measurements are analyzed for indications of being adequately settled at a rest stage and displayed).

Regarding claim 18, Forstner discloses the assessment arrangement is designed for detecting at least one of a pulse period progression, a pulse amplitude progression, pulse forms from the pulse oscillogram (PO), a formation of the assessment criteria from the pulse period progression, a pulse amplitude progression, and a pulse form change (see p.2 Lns. 52-56 where pressures and pulse rates are measured oscillometrically and analyzed over time for steady

increasing and decreasing patterns, p. 3 Lns. 29-31 where a variation index of results of blood pressure and pulse rate are determined for a series of data).

Regarding claim 30, Forstner discloses as the assessment criteria for the hemodynamic stability the analysis of the pulse shape includes a determination of at least one rise at least at one point of at least one of an ascending flank and a descending pulse flank, and a chronological change in the rise at the respective points or a ratio of the rises at least at two points of a pulse is checked for different pulses (see p.2 Lns. 52-56 where pressures and pulse rates are measured oscillometrically and analyzed over time for steady increasing and decreasing patterns, p. 3 Lns. 29-31 where a variation index of results of pulse rate are determined for a series of data).

Regarding claim 31, Forstner discloses for forming the assessment criteria, at least one of the pulse period progression, the pulse amplitude progression (PA) and the pulse shape is weighted one of identically and differently depending on a markedness (see p.2 Lns. 52-56 where pressures and pulse rates are measured oscillometrically and analyzed over time for steady increasing and decreasing patterns, p. 3 Lns. 29-31 where a variation index of results of blood pressure and pulse rate are determined for a series of data).

Regarding claim 34, Forstner discloses a diagnosis of the hemodynamic instability is an automated correction of the error effects (see p.2 Lns. 52-56 where pressures and pulse rates are analyzed over time for steady increasing and decreasing patterns, and p. 4 Lns. 14-20 where results above the set limits are averaged to form a corrected value to reduce the affects of artifacts).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 6, 7, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forstner (Forstner, EP 1,258,223) as applied to claims 1-5 and 23 above, and further in view of Diab (Diab, US 6,463,311).

Regarding claims 6 and 24, the limitations are fully met by Forstner, except the limitation of "pulse period lengths of at least a starting range and an end range of the pulse oscillogram (PO) are compared with each other, and a deviation of the pulse period lengths of a starting range ($T_{initial}$) and an end range ($T_{terminal}$) is made a basis of the assessment criteria" is not included.

However, Forstner teaches that resulting measurements are verified that pulse rates are either steadily decreasing or increasing (p. 2 Lns. 52-56), and a variation index of results of pulse rates are determined for a series of data (p. 3 Lns. 29-31), while Diab teaches the usage of a ratio

checker that compares the ratio of ascending to descending portions of the pulse signal to a threshold (see col. 8 Lns. 34-48). To include a pulse period deviation assessment criteria Forstner would need to be programmed with the teachings of Diab to include the ratio checker.

It would have been obvious to one of ordinary skill at the time of the invention to modify Forstner with Diab to include a ratio checker for comparing the difference in time lengths of the pulse periods in order to remove pulses that do not meet a set threshold of a typical physiological pulse (see Diab col. 8 Lns. 38-41); thus, the inclusion of a comparison of pulse period component times used as assessment criteria is an obvious mechanical expedient.

With regards to claim 7, the limitations are fully met by Forstner with Diab as in claim 6 above, where Diab discloses a deviation of the lengths of the pulse period is calculated by the pulse oscillogram (PO) as a difference of lengths of the periods of the starting range and the end range as a function of a mean pulse period length of the pulse oscillogram (see col. 8 Lns. 34-48 where usage of a ratio checker that compares the ratio of ascending to descending portions of the pulse signal to a threshold, and see col. 4 Lns. 46-48 where a pulse statistic subprocessor calculates a mean pulse period as an output).

With regards to claim 25, the limitations are fully met by Forstner, except that the limitation of "a deviation of the lengths of the pulse period is calculated by the pulse oscillogram (PO) as a difference of lengths of the periods of the starting range and the end range as a function of a mean pulse period length of the pulse oscillogram" is not included.

However, Forstner teaches that resulting measurements are verified that pulse rates are either steadily decreasing or increasing (p. 2 Lns. 52-56), and a variation index of results of pulse rates are determined for a series of data (p. 3 Lns. 29-31), while Diab teaches the usage of a ratio checker that compares the ratio of ascending to descending portions of the pulse signal to a threshold (see col. 8 Lns. 34-48), and the usage of a pulse statistic subprocessor that calculates a mean pulse period as an output (see col. 4 Lns. 46-48). To include a pulse period deviation assessment criteria Forstner would need to be programmed with the teachings of Diab to include the ratio checker and the processor to determine a mean pulse period.

It would have been obvious to one of ordinary skill at the time of the invention to modify Forstner with Diab to include a ratio checker for comparing the difference in time lengths of the pulse periods and a mean pulse period in order to remove pulses that do not meet a set threshold of a typical physiological pulse (see Diab col. 8 Lns. 38-41); thus, the inclusion of a comparison of pulse period component times and a mean pulse period used as assessment criteria is an obvious mechanical expedient.

20. Claims 11-13 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forstner (Forstner, EP 1,258,223) as applied to claims 1-10 above, and further in view of Goto et al. (Goto, US 2003/0092999).

Regarding claims 11 and 29, the limitations are fully met by Forstner, except that the limitation of "a rise (α) in an ascending branch of one of an envelope and a rise (β) in a descending branch, a plateau width (PL) around a maximum, or a combination of at least two of these characteristic values from the pulse amplitude progression each is used as a characteristic value for forming the assessment criteria" is not included.

However, Forstner teaches the usage of variation indices of results of blood pressure and pulse rate determined for a series of data (p. 3 Lns. 29-31), and where Goto teaches that the angle of ascent changes depending on applied cuff pressure, where the pulse wave shortens and does not allow for high accurate blood pressure readings when the cuff pressure is low (see [0043] and Figure 6), and Goto teaches that the computer determines a systolic blood pressure when the pulse amplitudes significantly change in phase in which the amplitudes increase and diastolic pressure when the pulse amplitude significantly change in phase in which the amplitude decreases, (see [0077]), and Goto teaches the usage of a computer to determine a point or time where the values L have significantly changed indicating an inflection point and is an indication of true diastolic blood pressure (see [0114], [0115], Figures 8 and 12). To determine one of the assessment criteria Forstner would need to be programmed to include in a variation index the values of blood pressures calculated as taught in Goto.

It would have been obvious to one of ordinary skill at the time of the invention to modify Forstner with the teachings of Goto to include indices of ascending angles and maximum/ minimum pressures determined inflection points as assessment criteria in order to determine more accurate blood pressure readings and identify change in measurements from oscillometric recordings; thus, the inclusion of different features of oscillometric curves used to assess errors or changes in measurements of blood pressure or pulse rate is an obvious mechanical expedient.

Regarding claim 12, the limitations are fully met by Forstner with Goto, where Forstner discloses as the assessment criteria for the hemodynamic stability the analysis of the pulse shape includes a determination of at least one rise at least at one point of at least one of an ascending flank and a descending pulse flank, and a chronological change in the rise at the respective points

or a ratio of the rises at least at two points of a pulse is checked for different pulses (see p.2 Lns. 52-56 where pressures and pulse rates are measured oscillometrically and analyzed over time for steady increasing and decreasing patterns, p. 3 Lns. 29-31 where a variation index of results of pulse rate are determined for a series of data).

Regarding claim 13, the limitations are fully met by Forstner with Goto, where Forstner discloses for forming the assessment criteria, at least one of the pulse period progression, the pulse amplitude progression (PA) and the pulse shape is weighted one of identically and differently depending on a markedness (see p.2 Lns. 52-56 where pressures and pulse rates are measured oscillometrically and analyzed over time for steady increasing and decreasing patterns, p. 3 Lns. 29-31 where a variation index of results of blood pressure and pulse rate are determined for a series of data).

21. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forstner (Forstner, EP 1,258,223) in view of Goto et al. (Goto, US 2003/0092999) as applied to claims 11-13 above, and further in view of Doten et al. (Doten, US 2002/0058875).

Regarding claim 14, the limitations are fully met by Forstner with Goto, except that the limitation of "at least one of a breathing frequency signal, an electrocardiogram signal and a skin impedance measurement signal each is determined and evaluated in regard to a chronological change during the individual blood pressure measurement" is not included.

However, Forstner with Goto teaches the use of a variation index of results of blood pressure and pulse rate are determined for a series of data (see Forstner p. 3 Lns. 29-31), while Doten teaches the usage of determining the respiration rate during blood pressure readings (see

Figure 3 and [0048]), and the usage of additional sensors such as an EKG (see [0032]). To determine respiration rate Forstner with Goto would need to be programmed to determine the respiration cycle and inverse respiration cycle from oscillometric readings as taught in Doten.

It would have been obvious to one of ordinary skill at the time of the invention to modify Forstner with Goto to include determination of respiration rate from oscillometric recordings as taught by Doten in order to achieve a more accurate indication of the respiratory affect on blood pressure, or other physiological signal correlations with blood pressure readings; thus, the determination of a correlation between physiological signals and blood pressure is an obvious mechanical expedient.

Regarding claim 15, the limitations are fully met by Forstner with Goto and Doten, where Doten discloses a breathing frequency signal is obtained from one of the analysis of the pulse oscillogram and by an additional sensor arrangement (see Figure 3 and [0048] where respiration rate is determined from oscillometric readings, and [0032] where multiple sensors can be used).

Regarding claim 16, the limitations are fully met by Forstner with Goto and Doten, where Forstner discloses a diagnosis of the hemodynamic instability is an automated correction of the error effects (see p.2 Lns. 52-56 where pressures and pulse rates are analyzed over time for steady increasing and decreasing patterns, and p. 4 Lns. 14-20 where results above the set limits are averaged to form a corrected value to reduce the affects of artifacts, abstract and Figure 1.1 where the results of measurements are analyzed for indications of being adequately settled at a rest stage and displayed).

22. Claims 19, 20, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forstner (Forstner, EP 1,258,223) as applied to claims 1, 17, 18 above, and further in view of Doten et al. (Doten, US 2002/0058875).

Regarding claims 19 and 20, the limitations are fully met by Forstner, except that the limitation of "the assessment arrangement detects at least one secondary physiological parameter correlating with a change of hemodynamics which relates to at least one of a breathing frequency signal, an electrocardiogram signal and a skin impedance signal" is not included.

However, Forstner teaches the use of a variation index of results of blood pressure and pulse rate are determined for a series of data (see p. 3 Lns. 29-31), while Doten teaches the usage of determining the respiration rate during blood pressure readings (see Figure 3 and [0048]), and the usage of using additional sensors such as an EKG (see [0032]). To determine respiration rate Forstner would need to be programmed to determine the respiration cycle and inverse respiration cycle from oscillometric readings as taught in Doten.

It would have been obvious to one of ordinary skill at the time of the invention to modify Forstner to include determination of respiration rate from oscillometric recordings as taught by Doten in order to achieve a more accurate indication of the respiratory affect on blood pressure, or other physiological signal correlations with blood pressure readings; thus, the determination of a correlation between physiological signals and blood pressure is an obvious mechanical expedient.

Regarding claim 32, the limitations are fully met by Forstner, except that the limitation of "at least one of a breathing frequency signal, an electrocardiogram signal and a skin impedance measurement signal each is determined and evaluated in regard to a chronological change during the individual blood pressure measurement" are not included.

However, Forstner teaches the use of a variation index of results of blood pressure and pulse rate are determined for a series of data (see p. 3 Lns. 29-31), while Doten teaches the usage of determining the respiration rate during blood pressure readings (see Figure 3 and [0048]), and the usage of using additional sensors such as an EKG (see [0032]). To determine respiration rate Forstner would need to be programmed to determine the respiration cycle and inverse respiration cycle from oscillometric readings as taught in Doten an include an index for the series or change in frequency of the values.

It would have been obvious to one of ordinary skill at the time of the invention to modify Forstner to include determination of respiration rate from oscillometric recordings as taught by Doten and include these readings in an index in order to achieve a more accurate indication of the respiratory affect on blood pressure, or other physiological signal correlations with blood pressure readings; thus, the determination of a correlation between physiological signals and blood pressure in time series is an obvious mechanical expedient.

Regarding claim 33, the limitations are fully met by Forstner with Doten, where Doten discloses a breathing frequency signal is obtained from one of the analysis of the pulse oscillogram and by an additional sensor arrangement (see Figure 3 and [0048] where respiration

rate is determined from oscillometric readings and [0032] where multiple sensors can be used).

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pinsky (US 2003/0167010) teaches a system with an algorithm for managing hemodynamically unstable patients. Silverman et al (US 2003/0233048) teaches a device for assessing the condition of a subject by measuring and characterizing one or more oscillatory activities of the subject. Takeda (5,425,372) teaches a device to measure arterial wall motion, arterial pressure and ECG. Warren et al. (US 5,156,147) teaches a variable rate pacemaker having an upper rate limit governor based on hemodynamic performance. Oka et al. (US 2003/0097074) teaches automatic blood pressure measuring apparatus which determines blood pressure of the subject based on a change of the corrected amplitudes of the cuff pulse wave. Nissila et al (US 6,554,773) teaches a device to measure diastolic blood pressure when the interpreting unit detects a change in a trend of a characteristic of the presence pulse indicative of magnitude. Narimatsu et al. (US 6,827,687) teaches a blood pressure measuring device having waveform analyzing function. Kolluri et al. (US 2002/0082507) teaches a device to measure blood pressure based on comparing oscillation time interval. Friedman et al. (2005/0004477) teaches a device for measuring blood pressure by comparing pressure oscillation. Flaherty et al. (US 5,791,347) teaches a device for motion intensive pulse detection including hemodynamic parameters. Forstner (US 2001/0049476) teaches a device for measuring pulse time differences and comparing these values with a predetermined reference value. Georgi (US 4,592,365) teaches the determination of phase difference in pulse rates and compares pulse period average

with individual pulse periods. Ramsey III (US 4,349,034) teaches a method for determining heart rate pulses are within a prespecified time limit by taking the time difference between a base of the heart pulse and a maximum. The applicant is reminded to review prior art submitted with the information disclosure statement received 4/3/2007.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL R. BLOCH whose telephone number is (571)270-3252. The examiner can normally be reached on 7:30-5:00 Monday-Thursday; Alternate Fridays 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571)272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/M. R. B./
Examiner, Art Unit 3735

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